President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

Suite 555, 2000 K Street, N.W., Washington, DC 20006 (202) 653-8051

June 17, 1981

The Honorable William J. Casey
Director
Central Intelligence Agency
Washington, D.C. 20505

Dear Mr. Casey:

In March 1980, pursuant to Section 1802(c) of the legislative mandate to this Commission (set forth in Title III of Public Law 95-622), I wrote to your predecessor requesting information regarding your agency's guidelines and regulations governing research with human subjects. Copies of that letter and your agency's response are enclosed. A draft summary of your policies and regulations, based upon your agency's response, is enclosed for your review prior to inclusion in our report to the Congress. Please let me know if the summary is accurate or, if not, what modifications should be made. If you have issued any policy statements or regulations on this topic subsequent to your last communication with this office, please so indicate and enclose copies with your response.

In addition to its responsibility to report to the Congress on the adequacy and uniformity of federal regulations for the protection of human subjects, this Commission is required to assess the adequacy of the implementation of such regulations, guidelines, policies, etc. To assist us in responding to this portion of the mandate, could you please provide a description of the following, to the extent applicable, and provide copies of relevant documents:

1. Policies or procedures (formal or informal) by which your agency evaluates or monitors the actual performance of agency or extramural Institutional Review Boards (e.g., reporting requirements, site visits, record reviews);

2. Standards and procedures to guide the investigation of complaints regarding the review or conduct of research involving human subjects;

3. The number and character of any such reports or complaints received in the last 5 years (FY 1976-1981); and

4. The manner in which these complaints were disposed of, the findings that were made, and the sanctions, if any, that were imposed.

We would appreciate receiving your response by August 1, 1981, so that the staff can prepare a summary and analysis of the response of all federal agencies and the Commission, in turn, can formulate any recommendations it may wish to include in its Biennial Report to the Congress, due December 31, 1981. I will be happy to answer any questions you or your staff may have regarding the preparation of your response. Please feel free to call me at 653-8051 if I can be of assistance. Thank you for your cooperation.

Sincerely yours,

Barbara Mishkin

Barbara Mishkin
Deputy Director

Enclosures

STAT cc: [redacted]
Liaison Officer

March 12, 1980

Dear :

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was established by Title III of Public Law 95-622 in November 1978. Section 1802(c) provides:

> (c) REPORT ON PROTECTION OF HUMAN SUBJECTS. The Commission shall biennially report to the President, the Congress, and appropriate Federal agencies on the protection of human subjects of biomedical and behavioral research. Each such report shall include a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such agencies, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

In addition, section 1803(d)(1) provides:

> The Commission may secure directly from any Federal agency information necessary to enable it to carry out this title. Upon request of the Chairman of the Commission, the head of such agency shall furnish such information to the Commission.

A copy of the Commission's mandate is enclosed.

At the request of Morris B. Abram, Chairman of the Commission, I am asking the head of each federal department or agency to advise this office as to whether any biomedical or behavioral research involving human subjects is supported or conducted under its auspices. For the purpose of this inquiry, please refer to the enclosed definition of research with human subjects developed by the National Commission for the Protection of Human Subjects.

If your department or agency does conduct or support such research, whether directly or indirectly, please provide the following additional information:

(1) A description of the nature and extent of such research;

(2) Copies of the regulations or guidelines that govern the conduct of such research;

(3) An analysis of the extent to which your regulations or guidelines conform to those of the Department of Health, Education, and Welfare (codified at 45 CFR 46, as amended in 43 Federal Register 51559, November 3, 1978);

(4) A description of your procedures for monitoring such research during the course of its conduct, and for assuring that the agency is informed of any untoward or unexpected events;

(5) A description of the nature and extent of any injuries or of any departures from approved protocols that have been reported or discovered, and the steps taken by your agency to investigate and resolve such problems;

(6) The views of your department or agency regarding recently proposed modifications to the existing HEW regulations, which have been published as follows:

43 Federal Register 31786 (July 21, 1978)
43 Federal Register 53950 (November 17, 1978)
44 Federal Register 47688 (August 14, 1979); and

(7) Any action taken by your department or agency with respect to the proposed modifications enumerated above.

As an aid in framing your response, you may wish to review the enclosed excerpt from the report of our predecessor, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The description relating to your agency was completed in late 1977, and confirmed by your agency staff as accurate prior to inclusion in the National Commission's report. In response to questions 1-4, above, indicate what changes, if any, are required for that description accurately to reflect the current status of your agency's activities and policies.

I am sure that you share with us an appreciation of the importance of our biennial report to Congress on this matter. Please feel free to call me at 653-8051 for further information or if we can be of any assistance. We hope to have all the responses in by May 1, 1980, in order to prepare a timely report to the Commission and to the Congress. If you are unable to prepare a complete report by that date, we would appreciate receiving a response to Questions (1), (2) and (4) by May 1, to be supplemented by the full response at your earliest convenience.

Sincerely yours,

Barbara Mishkin
Acting Director

Enclosure